

**REMARKS**

Review and reconsideration on the merits are requested.

**Formal Matters**

Applicants appreciate the Examiner entering their Preliminary Amendment, approving the drawings, and acknowledging receipt of the certified copies of the priority documents (there are two priority documents).

**Claim Objections**

The corrections the Examiner suggests have been made.

Withdrawal of the objection to claims 2-11 is requested.

**Pending Claims**

At the time of rejection, claims 1-19 were pending.

All of these claims are still pending.

**Claim Amendments**

Claims 2-11 are amended. No other claims are amended.

**Request for Interview**

If this application is not in condition for allowance, a telephone interview is requested.

**The Prior Art**

U.S. 6,538,152 Tanaka et al (Tanaka); U.S. 6,720,014 Short et al (Short); U.S. 6,262,115 Guittard et al (Guittard).

**The Rejection**

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tanaka in view of Short and Guittard.

The Examiner's position on the prior art and application of the claims herein to the prior art is set forth in the Action and will not be repeated here except as necessary to an understanding of Applicants' traversal which is now presented.

### **Traversal**

Referring to the present specification at page 1, lines 18-22, the symptoms of overactive bladder (OAB) are defined as follows:

“The symptoms of OAB are **imperative urinary urgency** with or without urge incontinence, generally but not necessarily combined with pollakisuria and nycturia. OAB is also characterised by involuntary detrusor contractions which are either triggered by provocation or occur spontaneously.” (bolding added)

Pollakisuria is frequency and nycturia is nocturia.

In addition, OAB is associated with involuntary contractions of the detrusor muscle. Accordingly, in Applicants' view, it is very important to suppress involuntary detrusor contractions as the main causative condition in treating OAB.

The present invention was completed based on the unexpected findings that certain phenoxyacetic acid derivatives suppress spontaneous small bladder contractions (involuntary detrusor contractions). Specifically, the present invention is directed to a method of treating OAB comprising administering a specified phenoxyacetic acid derivative which is a  $\beta_3$ -adrenoceptor stimulant. See, in this regard, Tanaka. The phenoxyacid derivative which is a  $\beta_3$ -adrenoceptor stimulant decreases the amplitude and frequency of the spontaneous small bladder contractions. See Examples 3 and 4 and Figs. 7-9. Tanaka in no fashion discloses that the compounds of the present invention will exhibit such effects.

Turning to Short and Guittard, these references refer to oxybutynin, a muscarinic receptor antagonist. However, since it was known that muscarinic receptor antagonists suppressed involuntary bladder contractions by blocking muscarinic receptor in the bladder, Applicants consider these references simply to teach that oxybutynin is effective in treating overactive bladder with the symptoms of urge urinary incontinence, urgency and frequency.

Thus, the combination of Tanaka/Short/Guittard in no fashion suggests that certain phenoxyacetic acid derivatives suppress small bladder contractions (involuntary detrusor contractions).

Further, if the Examiner will refer to Example 4, it can be seen that the compounds of the present invention have stronger decreasing effects on the amplitude and frequency of spontaneous small bladder contractions than those of tolterodine, a known muscarinic receptor antagonist. The Examiner's attention also is directed to Figs. 8 and 9. However, such muscarinic receptor antagonists do not affect the micturition pressure, unlike tolterodine. The Examiner is requested to review Fig. 10.

Applicants respectfully submit that based on the superiority established in the specification, even if the Examiner has posed a case of *prima facie* obviousness, Applicants have rebutted the same.

Withdrawal is requested.

**The Provisional Obviousness-Type Double Patenting Rejection**

As only provisional, Applicants do not address the provisional rejection on the merits at this time.

AMENDMENT UNDER 37 CFR § 1.111  
U. S. Application No. 10/809,346

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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